

# MANUFACTURING EXTENSION PARTNERSHIP

## Success Stories from the Field

### Windstone Medical

#### Montana Manufacturing Extension Center

#### Windstone Medical Bundles Quality and Lean to Meet Growing Demand

##### Client Profile:

WindStone Medical Packaging, Inc. (WMI) was founded in 1978 as Cardio-Pak and acquired by Bekins Logistics in the fall of 2003. The Billings, Montana, company fills orders for custom procedures trays (CPTs), accurately, completely sterilized, and on demand. WMI offers 400 different packs with 6,000 different stocking items from which to select. It is unique in that it sterilizes individual packs and not in large batches. Items are humidified for 24 hours before CPT's are made up and wrapped in a clean room environment where everyone wears protective gear including lab coats, hair and shoe covers and even mustache covers when needed. Each pack is then vacuum sealed and injected with ETO (ethylene oxide) gas before being placed in special heat-controlled chambers where the ETO kills any contaminants. WMI uses controlled air chambers where heated air works as an accelerant for the sterilizing gas. The minority-owned company achieved certification to the ISO 9001:2000 standards in May, 2005, and employs 45 people.

##### Situation:

With changing ownership, WMI expanded into new markets and wanted to implement Lean techniques to improve space utilization and flow. A bottleneck with its on-site sterilization production facility was identified. Additionally, the company intended to certify to the newer ISO quality standard, now required by customers. This is one of the ways WMI differentiates itself from competitors. Without it, a portion of its business could have been lost. WMI contacted the Montana Manufacturing Extension Center (MMEC), a NIST MEP network affiliate, for help.

##### Solution:

A team of three MMEC field engineers assisted on the quality/Lean project. An ISO gap analysis and conversion plan were provided to compare WindStone's compliance against the new standards, which are much more customer focused. A readiness audit helped the company check its progress on the conversion, and a final audit and check off of corrected non-conformance areas prepared them for the official visit by ISO registrars this spring. WMI is also FDA regulated, so those requirements were mapped together with the ISO requirements so they would complement each other. WMI has also been working with MMEC on several other projects, including implementing Lean Manufacturing techniques, to complement the logistics expertise the Bekins tie-in brought to the table and improving a bottleneck in the sterilization process. The company uses controlled air chambers where heated air works as an accelerant for the sterilizing gas injected into each pack. The process was taking five days. MMEC brought in environmental and engineering specialists to solve the issues that were creating the bottleneck. Key options identified were to increase airflow or temperature. A well thought out quality system, clear procedures, fast turnaround using Lean techniques, and a user-friendly website for purchasers is helping WMI meet growing demand across the nation for its products.

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### Results:

- \* Reduced sterilization cycle from 5 to 3 days as result of increase in airflow and temperature in sterilizing rooms.
- \* Reduced cycle time, from time packs are built, sterilized and shipped, by 60 percent.
- \* Relocated warehouse off-site, with employees using a batch build sheet to pick daily from the warehouse.
- \* Developed format for new company ISO manual that uses more flowcharting, photos and graphics and less text.
- \* Implemented visual control system which aids workers in visually checking that every pack is accurately loaded, and trains new workers more effectively than written checklist.

### Testimonial:

"MMEC really helped clear up some flow problems and released congested areas so we are not crossing back and forth across the plant like we used to. Things have changed from jumbled, frustrating, and hard work to smooth and much less work. "MMEC had the knowledge and resources to meet our requirements. They took the time to understand our processes and our boundaries and worked to fit the requirements of the new ISO standards to our particular business. They were honest and forthcoming during our readiness audits, identifying our "gaps" and giving valuable suggestions as well as assistance when needed."

Vikki Fosjord, Operations Manager